Original Article

Validating the Efficacy of Yogic Practices on Pre Menstrual Syndrome in Young Adults. A Randomized Controlled Trial

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ABSTRACT

Background: Yoga has been used as a remedial treatment for ailments of Premenstrual Syndrome (PMS). The combined practices of yoga can be used as a systematic measure to overcome PMS to have a harmonious living. **Aims & Objectives:** The objective of this study was to validate the efficacy of yoga practices for PMS and to evaluate the effect of yogic practices for PMS on PSST-A. **Materials and Methods:** A total of 60 Premenstrual syndrome subjects aged 16-23 years were screened and after filling inclusion criteria as well as diagnostic criteria 39 subjects were recruited to the study. Pre assessments were made before the treatment. Expert validated yoga practices was given for the duration of 45 minutes each for 15 days. Post assessments was taken after the successive menstrual cycle of the intervention. All the details of the study were explained and consent was obtained from the subjects. **Result:** From PSST-A recordings, significant differences were detected in premenstrual symptoms. Subjects reported that there is a greater improvement in their sleep quality and daily living by reducing symptoms intensity and duration for combined yogic practices. Post analysis indicated PSST-A was improved from baseline ($p < 0.05$), with reduction in the symptoms for the combined effect of yogic practices. **Conclusion:** This Yoga module is effective for the treatment of PMS. Significant differences has been found before and after the treatment. Hence combined practices of yoga plays a significant role in reducing the symptoms of PMS.

Key Words: Premenstrual Syndrome, Yoga Protocol Validation, Premenstrual Syndrome Impact, Yogic Practices.

In the modern world non-communicable diseases are increasing due to various external factors like pollution, fast foods, and adulterated drinks etc. Among the internal factors stress is one of the most highlighted factor in the cause of disease[1]. Yogis have shown us the path to achieve harmony by different techniques. "Yoga" is an ancient Sanskrit word which, in only two syllables, encompasses the entire body of different experiences and experiments of thousands of realised masters. The word Yoga is commonly translated as "union". It implies that an individual is to be united with the Universe, his personality with the Universality. The root word "Yuj" which means "to join together". The English word 'yoke" is directly derived from the Sanskrit word Yuj [2]. Yoga is a complex intervention that includes physical movement, breathing techniques, meditation, visualization and philosophical underpinnings that may influence attitudes, beliefs and social interaction [3]. The aim is to attain liberation- moksha by self-realization. It works in all aspects physical, emotional, intellectual and spiritual. Yoga brings in harmony by achieving the state of mind and body in tune with each other. The primary step to achieve it is through breathing exercises where the synchrony between breath and body movements is the key [4].

In the process of physiological development women undergo various changes in their physicality and mentality. From the age of adolescence to adulthood is the vital phase in which many hormonal variations tend to disturb their daily living among which PMS is a common disorder in females of reproductive age. It is a cluster of physical and psychological symptoms. Pain, muscle cramps, fatigue, myalgia, are some of the physical symptoms and depression, anxiety, anger, forgetfulness are the psychological manifestations [5]. The prevalence has been reported in 20 to 32% of premenopausal and 30 to 40% of the reproductive female population.

Previous Indian studies have found a 20% prevalence of PMS in the general population and among those 8% had severe symptoms [6]. PMS occurs during the luteal phase of menses,

Access this article online

Received – 20th Dec 2023

Initial Review – 22nd Jan 2024

Accepted – 28th Jan 2024

Quick Response Code

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however, it disappear with menstrual flow. It affects the daily lives of women and can deteriorate their quality of life and social skills. The severity of symptoms is associated with its duration in how it impairs the daily lives of women [7]. Hormonal medications are often used to relieve typical PMS-related symptoms. These medications suppress the production of certain hormones made naturally in the body and interfere with the menstrual cycle. Other medications used include antidepressants, diuretics, analgesics and anti-anxiety drugs. There are a lot of hormonal contraceptives, containing different hormone combinations. There hasn't been enough research to be able to say which of these can help against PMS. A type of antidepressant called selective serotonin reuptake inhibitors (SSRIs) are typically used. These medications increase the concentration of a neurotransmitter in the brain called serotonin. It may influence the way in which women's body react to certain hormones that are released in greater amounts before menstruation [8]. Pharmacological treatment have few adverse effect like weight gain, antidepressant induced sexual dysfunction, affect metabolism [9].

Yoga helps in relieving symptoms of PMS by reducing stress there by down regulating the hypothalamic pituitary adrenal axis and the sympathetic nervous system activity leading to pain [10]. Though there are several pharmacological treatment modalities available for treating PMS have shown several adverse effect. Yoga is a non-pharmacological intervention which does not have any known side effects or adverse effect till date. The objective of this study is to validate the yoga practices and also explore the effect these practices on females affected with PMS.

MATERIALS & METHODS

Yoga Module Validation: Yoga practices have been selected from classical yoga texts (Gheranda Samhita, and Hatha Yoga Pradipika, with contemporary yoga-related books, yoga therapy series-yogic management of diseases) and scientific literature for treating the clinical features of PMS have been used as the source of information for framing the yoga protocol. The selected yoga practices for mild, moderate and severe PMS include simple loosening exercises, breathing techniques, asana (postures), pranayama (breath regulation) and relaxation. A questionnaire with selected yoga practices has been sent to 45 experts electronically by email with Google form for obtaining their opinion on a three-point Likert scale (1= not necessary, 2= useful but not essential, 3= essential) for validation. Additional questions have been added to have their opinion on the same practices. Experts were medical professionals in yoga, who either practiced or treated patients with yoga. After incorporating the comments of the expert, final yoga protocol for PMS was developed. Content validity ratio (CVR) for each practice was calculated using Lawshe's law for the validation, and those with CVR $\geq$ 0.6 have been included in the final protocol (i.e., marked $\geq$ 80% Essential by experts) [11].

CVR= (ne−n/2) / (n/2). Where ne = number of experts indicating "essential", n = total number of experts.

Study design: This was an open-label randomized control trial.

Participants: A total of sixty under graduate college students were screened. Thirty nine subjects with age group ranging between 16-23 years who fulfilled the inclusion and diagnostic criteria participated in study. They were randomly divided into 2 equal groups using computerized randomization method. Study group n=20 and control group n=19. Pre assessments were recorded for both the groups. Study group practiced yoga protocol for 50 minutes daily for 15 days. For control group shavasana was given for 50 minutes. Every session was practiced under the guidance of yoga therapy consultant. Post assessments were recorded immediately after completion of next menstrual cycle. All the information about the study was explained to the subjects and consent was be obtained from all the participants before starting the study. Ethical clearance was obtained from Institutional Ethical Committee. The subjects for the study was recruited from Alva's College of Naturopathy and yogic sciences and Alva's Anandamaya Naturopathy and Yoga hospital, Moodbidri 574227, Dakshina Kannada dist, Karnataka, India.

Inclusion & Exclusion Criteria: Subjects aged 16 to 23 years females having PMS in luteal phase of menstrual cycle who are willing to participate in the study were included. Subjects who had practiced yoga for previous 6 months, on active pharmacological/ herbal medications, history of hospitalization due to any health related issues in previous 6 months, with co-morbidities, drinking alcohol or smoking cigarettes, history of PCOD and history of any menstrual disorders other than PMS were excluded from the study.

Intervention & Assessment tool: Yoga intervention is selected from 4 categories, (1) Breathing exercises, (2) Yogic postures, (3) Pranayama, (4) Relaxation. Breathing exercises for bringing harmony between mind and body. Yogic postures are chosen to reduce physical symptoms of PMS. Pranayama for tranquilizing and relaxing effect. Relaxation technique for reducing stress. The premenstrual symptoms screening tool for adolescents (PSST-A) questionnaire being the assessment tool [12]. The tool translates DSM-IV criteria into a rating scale with degrees of severity, providing a quick and practical way to assess the severity and impact of premenstrual symptoms.

Statistics: The data was collected using two primary outcome variables. The baseline data was collected before the intervention and the post data was taken after the successive menstrual cycle. The data was organized in Microsoft excel sheets (version 2010). Data was analysed using IBM SPSS 26.0. The data was analysed for normality. For all the analysis, we present 95% confidence intervals and considered $p < 0.05$ as significant.

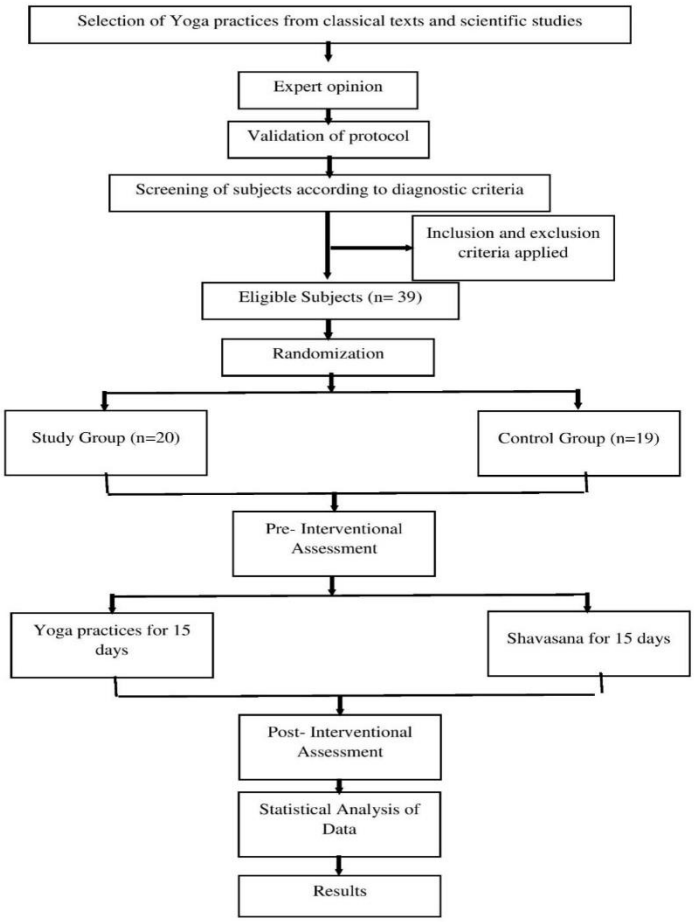

Figure 1: Illustration of Study Plan

RESULTS

Yoga Module Validation: All experts (n = 45) provided their opinion on the selected yoga practices to be followed for PMS. Table 4 show the validation of the identified yogic practices for PMS. For PMS, out of 16 practices, the majority of them accepted 14 practices as ≥ 80% essential (CVR ≥ 0.3), whereas 2 practices were considered to be less essential or not necessary (CVR ≤ 0.3) [13].

Clinical Trial: The data was visually inspected for manual typographic errors. The shapiro-wilk's test for Normality showed that the data was normally distributed. Paired samples t-test was used to assess within group differences. ANCOVA was performed to assess between group changes controlled for their respective baseline values. Levene's test for equality of variances were performed. The below table represents the descriptive statistics of variables of study and control groups. The following data shows the demographic data of participant's n. Within group changes showed a significant reduction in PSST-A ($p \leq 0.05$)

Descriptive Statistics:

Excluding the practices 5 and 6 due to low CVR value
Average CVI value after exclusion: 0.77
Intra class correlation was assed using SPSS Version IBM SPSS 26.0 Average value: 5.34

Table 1: Represents the expert responses, CVR value and the practices included or excluded in the study.

Yogic Practices	Responses	Expert Opinion			CVR	Selection
		Essential	Useful but not Essential	Not necessary		
Gulphavistara shvasanam (Ankle stretch breathing)	45	32	12	01	0.42	Included
Hasta ayama shvasanam (Hands in and out breathing)	45	33	9	3	0.51	Included
Vyaghrasana shvasanam (Tiger breathing)	45	43	2	0	0.91	Included
Ardha kati chakrasana (Side stretch pose)	45	34	10	1	0.51	Included
Eka padasana (One foot pose)	45	14	13	18	-0.37	Excluded
Padahastasana (Forward bending pose)	45	27	18	0	0.2	Excluded
Purṇa titali asana (Full butterfly exercise)	45	44	1	0	0.9	Included
Shashankasana (Rabbit pose)	45	43	2	0	0.91	Included
Ushṭrasana (Camel pose)	45	40	5	0	0.77	Included
Dhanurasana (Bow pose)	45	38	5	2	0.68	Included
Tiriyak bhujangasana (Twisting cobra pose)	45	39	5	1	0.7	Included
Setu bandhasana (Bridge pose)	45	44	1	0	0.9	Included
Supta udarakarshanasana (Sleeping abdominal stretch pose)	45	45	0	0	1	Included
Quick relaxation technique (QRT)	45	41	4	0	0.8	Included
Bhramari Pranayama	45	43	2	0	0.91	Included

(Humming bee breath) Nadi shuddhi Pranayama (Psychic network purification)	45	43	1	1	0.91	Included

Table 2: Paired t-test of Study and Control group

	Study				Control			
	Pre (Mean ±SD)	**Post (Mean± SD)**	**df**	**p- Value**	**Pre (Mean ± SD)**	**Post (Mean ± SD)**	**df**	**p- Value**
Age	21.3 ± 3.31				20.10 ± 2.57			
PSST-A	30.05± 10.32	16.65 ± 5.14	19	0.000	27.5 ± 10.09	27.53 ± 9.88	18	0.790

Between group changes performed using analysis of covariance (ANCOVA) for variables of interest adjusted for their respective baseline values indicated a significant difference in PSST-A showed $F_{(1, 57)}= 113.854$, $p\leq0.05$, $p\eta^2 = 0.76$

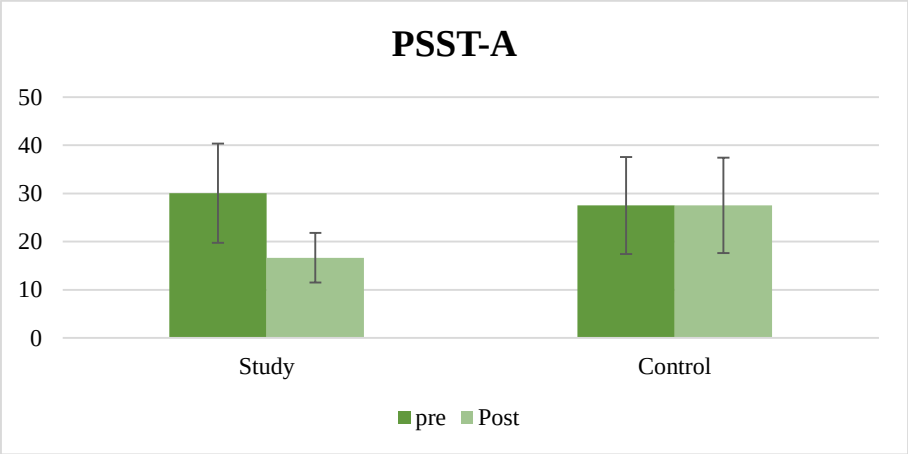

Figure 2: Graphical representation of PSST-A assessment

DISCUSSION

Efficacy of yoga practices has been demonstrated in the literature among the PMS females however, no study has validated a yoga protocol. The present study aimed to validate yoga practices and find the efficacy of these practices on PMS. A total of 39 patients with PMS participated in the present study, and the results revealed significant reduction in PMS symptoms measured by PSST-A in both groups. Nowadays, western therapies, in addition to complementary and alternative medicines, are unable to provide enough satisfaction for women suffering from PMS [14, 15, 16].Yoga has been shown in studies to reduce the various symptoms of PMS by improving the benefits of relaxation and nervous system control. According to a study, hatha yoga increases relaxation of the mind and body, reduces muscle tension and stress, and hence improves sleep with less anxiety. Hatha yoga study also looked at key symptoms and discovered that hatha yoga exercise reduces sympathetic activity, tension, and enhances calm in women with PMS. Sedation exercise has been demonstrated to alleviate PMS symptoms induced by stress and has also revealed that 80% of patients who did yoga practice improved their irritation symptoms [17].

According to Mahin Kamalifard et al. [18] Yoga exercise reduced symptoms in women with PMS during their normal reproductive cycle. Women felt calmer with less pain, their quality of life improved significantly. As a result, medical treatment may only be required in extreme cases. The study by Wen-Lan Wu et al on effect of yoga on cognitive measures on PMS women showed the difference in alpha wave % between follicular phase and luteal phase, as well as before and after exercise. The fraction of alpha waves changed after yoga exercise. In another study, PMS symptoms such as anger or irritability, anxiety or stress, crying or rising sensitivity to negative issues, depressed mood or hopelessness, loss of interest in work activities, house activities and in social activities, concentration problems were reduced in the yoga group. Deep breathing exercises has shown to reduce 'tension anxiety' and weariness in a study conducted by Hayama and Inoune [19]. Scientific literature reports remarkable positive effects induced breathing exercises on by forced expiratory volume [20] and maximum vital capacity [21]. Valentina Perciavalle et al found that deep breathing improved both the physiological impacts (heart rate and salivary cortisol levels) and in mood and perceived stress. Thus relieving the symptoms of PMS caused due to stress.

Stimulating asans and environmental enrichment all help increase hippocampus cells. Study by Chris et al found that experienced yoga practitioners' brain GABA levels increased by 27% following a 1-hour yoga asana practice [22]. The consistent practice of asana has the potential to induce chemical alterations in the blood and central nervous system. The serotonin levels in the body increase through asana and exercise, and this neurotransmitter is capable of crossing the blood-brain barrier, which can lead to mood elevation [23].

Yogic exercise also stimulates the release of endorphins, which are the body's natural painkillers. However, previous studies have shown that endorphins cannot cross the blood-brain barrier, and therefore have little effect on depression. Yogic exercise may also aid in the release of phenyl ethylamine, which is converted to phenyl acetic acid, further enhancing mood and alleviating depression [24].

A study aimed to investigate the effect of anuloma-viloma on PMS revealed the significant reduction in sympathetic activity and increased relaxation response that have effective reduction in symptom score [25]. The study by V. Pratap et al propose that a neural mechanism elucidates pranayama may impact cortical activity, resulting in a dampening effect that likely leads to a steadying of the mind. The description of this practice indicates that it elicits a potent Hering-Breuer reflex. This phenomenon is common to all breathing practices that involve periods of inspiratory pause after a full, deep inhalation. The afferent limb of the Hering-Breuer reflex comprises stretch receptors in the lung that become stimulated during inspiration. The resulting impulses ascend via the vagus nerve to the Pontine Apneustic Center, where they typically inhibit inspiration and promote expiration. The excessive stimuli evoked by this breathing practice may modify certain regions of the ascending reticular activating system, leading to a suppression of sensory input to the cortex and ultimately a steady state of mind [26].

The study on bhramari pranayama analysed to conclude that the epileptiform-like waves recorded during the pranayama can be regarded as indicative of non-epileptic hypersynchrony and suggests that a month of training is adequate to sustain this activity for a few minutes after bhramari pranayama. However, the manner in which this activity could impact the brain and potentially elicit a subjective experience such as "bliss" remains largely speculative [27]. The investigations conducted by Maniscalco et al have reported a notable increase in basal NO levels among healthy individuals during humming in comparison to silent exhalation. It has been established that the paranasal sinuses, specifically the maxillary sinus, play a critical role in the production of Nitric oxide (NO). The findings of their study have demonstrated that the output of NO during humming is substantially increased by a factor of 15 when compared to exhalation conducted in a quiet manner [28]. Endogenous NO in upper respiratory system affects physiology and pathology. Paranasal sinuses produce major part of NO. It regulates host defence and pulmonary functions. Humming during exhalation and bhramari panayama enhances endogenous NO generation [29]. Physical aspects of sinuses affect NO release and physiological functioning. Symptoms of PMS may be associated with NO release. Many studies have reported that the NO pathway contributes to the pathophysiological mechanism of PMS. Women with PMS have lower NO levels. A Study by Khadijeh et al showed that curcumin intake leads to reduced severity of pain in PMS and decrement in NO concentrations, which are significantly correlated. By the practice of bhramari pranayama enhances NO production there by decreasing the symptoms of PMS [30].

A study by Georgia Kolokithas et.al demonstrated that relaxation techniques reduced mood changes and improved PMS symptoms. The present study aims to confirm this, revealing relaxation improved symptoms and significantly reduced depressive symptoms and stress and anxiety disorder. One of the study found that relaxation training was effective in reducing symptoms of a particular syndrome, as well as fatigue and the use of tranquilizers [31]. Terry et.al, determined that relaxation, exercise, and lifestyle changes were the most effective methods for improving symptoms of PMS. QRT is one of the most effective relaxation technique that has proven to provide physical and psychological relaxation. The findings by Jilmy Anu Jose aid in recognizing QRT as a crucial measure in alleviating chest tube removal among postoperative coronary artery bypass grafting patient's related discomfort [32]. Since PMS without treatment can cause problems and affect the quality of life of women, it is essential to look for tools and treatments that can relieve the individual off PMS that are affordable. The results showed that the yoga protocol is a peaceful and effective approach for decreasing PMS symptoms. Therefore, this protocol could be recommended for women with PMS.

Strengths of the Study: No dropouts, no documented adverse effects, statistically significant result, this is the first study to provide validated yoga protocol for PMS.

Limitations & Drawbacks of the Study: Smaller sample size. Subjective variables were used which tend to have bias, short time intervention.

Future Prospects Emerging Through this Study: Future studies must have better objective variables to augment the reported benefits of this study. Study can be done with larger sample and longer follow- up**.** The study intervention of 3 months duration could have a long term impact.

CONCLUSION

The study results showed that there was reduction in pain, tenderness, swelling of breasts, stress reduction, decreased body pain following yoga practice which can be used as a reasonable alternative method in treating patients with premenstrual syndrome. The study highlights the significant role of combined yoga practices in reducing PMS symptoms and emphasizes the role of yoga as a systematic measure for overcoming PMS. Relaxation techniques have been shown to improve PMS symptoms, reduce depressive symptoms, and alleviate stress and anxiety disorders. Deep breathing exercises have been found to reduce tension anxiety and weariness, improving physiological impacts and in mood. Yoga asanas and environmental enrichment increase hippocampus cells and brain GABA levels, leading to chemical alterations in the blood and central nervous system. Yogic exercise stimulates the

release of serotonin and endorphins, enhancing mood and alleviating depression. Anuloma-viloma pranayama have been shown to reduce sympathetic activity and increase relaxation response, effectively reducing PMS symptoms. Bhramari pranayama increase endogenous NO generation, which can impact physiology and pathology. The yoga protocol is a peaceful and effective approach for decreasing PMS symptoms and can be practiced with ease.

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How to cite this article: Amshuman R Yadav, Archana K, Swathi KV, Prajwal HM, Shravya CN, Swathi S. Validating the Efficacy of Yogic Practices on Pre Menstrual Syndrome in Young Adults. A Randomized Controlled Trial. Indian J Integr Med. 2024; 4(1):12-17.

Funding: None; Conflicts of Interest: None Stated